IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 08-948 (LDD)
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

PLAINTIFFS' BRIEF IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION

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Dated: May 26, 2009

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I. INTRODUCTION

Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC (collectively "Pfizer" or "Plaintiffs") hereby oppose defendants Apotex Inc.'s and Apotex Corp.'s (collectively "Apotex" or "Defendants") Motion to Dismiss for lack of personal jurisdiction (hereinafter "Motion to Dismiss") (D.I. 28). Apotex's Motion to Dismiss should be denied because the exercise of personal jurisdiction over Apotex Inc. meets the requirements of both the Delaware Long-Arm Statute and the Due Process Clause of the United States Constitution.

By their motion, the Apotex entities persist in their manipulation of the judicial process, picking and choosing courts and judges to suit their purposes. Apotex admits that it has not contested jurisdiction in Delaware in nine of the past eleven cases where Apotex Inc. has been a party. (D.I. 29 ["OpenBr"] at 17-18.) Nevertheless, in *this* case, Apotex Inc. maintains its stubborn resistance to this Court's jurisdiction. Apotex's game of jurisdictional Whac-A-Mole is an obvious attempt to deny Pfizer (a Delaware corporation) the ability to seek redress for Apotex's patent infringement torts (committed and causing damage in Delaware) in the Delaware courts.

Apotex's ultimate goal is to have this case heard in Illinois even though Apotex has not and cannot identify a single document, witness, or event located in Illinois related to this case. There comes a point when Apotex's conduct, both specifically and generally, impacts the citizens of Delaware to such an extent that Apotex's selective evasions of the Delaware courts must end. As we demonstrate, this point has now been reached. Consequently, Apotex's Motion to Dismiss should be denied and this case should proceed in Delaware where Pfizer first filed the suit.

In the event the Court declines to deny the motion, Pfizer seeks leave to conduct limited jurisdictional discovery. Moreover, regardless of grant or denial of the motion, Apotex has failed in any event to establish that dismissal of this case under Rule 19 is appropriate. Rather, should personal jurisdiction over Apotex, Inc. be found lacking, the case should be transferred to Illinois where it can be consolidated with the Illinois case.

II. NATURE AND STAGE OF THE PROCEEDING

Because Pfizer filed an amended complaint in this Court on March 23, 2009 (D.I. 25)[1], Apotex withdrew its original Motions to Dismiss (D.I. 9) and Transfer (D.I. 11) as moot. Apotex has now filed a new Motion to Dismiss (D.I. 28) and a new Transfer Motion (D.I. 32) in lieu of answering Pfizer's amended complaint.[2] This is Pfizer's opposition to Apotex's renewed Motion to Dismiss (D.I. 28).

Regarding the concurrent Illinois case, *Pfizer Inc., et al. v. Apotex Inc., et al.*, No. 1:08-cv-07231 (Dow) ("Illinois Action"), Pfizer has moved to stay that case and the briefing for that motion was completed on April 27, 2009. Additionally, because Apotex opposed the filing of an amended complaint in the Illinois Action, the two cases are not presently identical. Pfizer has moved to amend its complaint in the Illinois Action and the briefing on this motion was completed on May 4, 2009. If the Illinois Court grants Pfizer's motion to amend its complaint, the Illinois Action will be reset and Apotex will then respond to the amended complaint.

III. SUMMARY OF ARGUMENT

1. Apotex's ANDA submission creates what has been called a "highly artificial" act of patent infringement. No actual infringement has yet occurred because Apotex does not have FDA approval to sell its copy of Lipitor®. Thus, at this time, there is no product actually being

[1] In the amended complaint, Pfizer added a count of patent infringement based on its newly granted U.S. Reissue Patent No. RE40,667 (the "RE667 patent"). Pfizer also provided additional jurisdictional allegations.
[2] Apotex has also filed a third motion for partial dismissal in response to Pfizer's amended complaint (D.I. 34.)

imported, made, used, or sold in the United States pursuant to the ANDA. Nonetheless, Apotex's patent infringement, while fictional in nature, creates a real and serious harm to Pfizer, a Delaware corporation. This harm thus occurs in Delaware. Apotex's ANDA submission is the sole and only basis for this litigation.

2. As required by statute, Apotex notified Pfizer of its patent infringement by a written letter pursuant to 21 U.S.C. § 355(j)(2)(B) ("ANDA notice letter"). Apotex sent its ANDA notice letter not only to Pfizer's headquarters in New York, but also to Pfizer's outside counsel in Wilmington, Delaware. In response to the grant of Pfizer's RE667 patent, Apotex sent another ANDA notice letter to Pfizer, again sending a copy to Pfizer's Delaware counsel. By law, Apotex's ANDA notice letters gave Pfizer the basis to bring this lawsuit and the letters are an essential part of Apotex's ANDA. Thus, Apotex knowingly and voluntarily created contacts with Delaware as an integral part of its ANDA submission which also contained a purported offer of confidential information to Pfizer's outside counsel. These acts are directly related to this lawsuit. The statutorily-mandated notice letters and offers of access were intended by Apotex to trigger Hatch-Waxman Act provisions. This activity supports specific jurisdiction in Delaware.

3. Patent infringement is a tort, and Apotex's ANDA submission constitutes a tort against Pfizer. Because Pfizer is a Delaware corporation, the tort has occurred in Delaware, the only place where the harm has occurred. No other act in the United States—apart from Apotex's self-serving appointment of its Illinois litigation counsel as its agent—provides any court with personal jurisdiction to hear this case. Apotex's ANDA submission supports specific jurisdiction in Delaware.

4. Apotex Inc. is a Canadian company claiming it has no physical presence in the United States. Apotex Inc.'s only business is generic medicines. An essential and necessary part of Apotex Inc.'s business is submitting ANDAs to the FDA seeking approval to sell copies of established pioneer drugs. Another critical part of Apotex Inc.'s operation is challenging the patent coverage (where applicable) on those medicines as permitted by the ANDA statute. In carrying out its business of generic medicines, Apotex Inc. has litigated its ANDAs in this Court many times in the past few years. And it has continuously and systematically availed itself of the legal protections of the State of Delaware by filing claims and counterclaims affirmatively seeking relief in other prior actions in this Court. This activity supports general jurisdiction in Delaware.

5. A significant amount of Apotex Inc.'s generic medicines is sold in Delaware and, on information and belief, Apotex Inc. derives substantial income from sales in this State. By one measure, its sales in 2008 alone exceeded $2.8 million. This activity supports general jurisdiction in Delaware.

6. Apotex Inc.'s substantial contacts with Delaware—contacts both related to this case and contacts in general—are such that exerting jurisdiction over Apotex Inc. does not offend traditional notions of fair play and substantial justice. To the contrary, permitting Apotex Inc. to conduct its substantial business in Delaware from behind the Canadian border while causing harm to Pfizer—a Delaware corporation—yet denying Pfizer's redress in the Delaware Court, all for the benefit of Apotex Inc., is an affront to fair play and substantial justice. Here, Apotex Inc. has reached from Canada into Delaware to infringe Pfizer's United States patents yet, in an effort to manipulate or game the ANDA system, Apotex Inc. claims that it can only be sued in the jurisdiction of its own choice—the Northern District of Illinois—where it has

authorized only one entity—its litigation counsel in Chicago, Illinois—as its agent for accepting service of process. Indeed, the only connection between the facts and substance of this case and the Northern District of Illinois is the presence of Apotex's litigation counsel. Had Apotex Inc. been driving a car in Delaware and hit a Delaware resident, there would be no question that this Court has personal jurisdiction. The fictional nature of Apotex's infringement does not mitigate the real and serious harm to a Delaware resident in this case and Due Process requires that Apotex Inc. not be permitted to harm Delaware residents without also being subject to jurisdiction in Delaware.

IV. FACTUAL BACKGROUND

A. Apotex's ANDA is the sole basis for this lawsuit

This lawsuit centers on Apotex's ANDA directed to the prescription drug atorvastatin.[3] (OpenBr at 7.) Pfizer is the sole holder of the FDA approval to sell atorvastatin in the United States which it sells in the form of a calcium salt under the trademark Lipitor®. (D.I. 25, ¶¶ 5-12.) Pfizer is the owner of U.S. Patent No. 5,273,995 ("the '995 patent") and the RE667 patent which claim, *inter alia*, the atorvastatin in Lipitor®. (D.I. 25, ¶¶ 10-11, Exs. A, B.) Apotex's infringement of Pfizer's '995 and RE667 patents is the sole basis for this lawsuit. (D.I. 25, ¶ 1; D.I. 31, Tao Decl., ¶ 18.)[4]

Apotex filed its Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to sell generic atorvastatin calcium tablets before the expiration date of the '995 and RE667 patents and certain other patents protecting Lipitor®. (D.I. 25, ¶¶ 17-18; D.I. 31, ¶¶ 18-

[3] Atorvastatin is a potent cholesterol lowering drug. Pfizer sells atorvastatin, in the form of its calcium salt, under the brand name Lipitor®. Lipitor® is and has been for many years, the world's best selling drug, with annual sales, world-wide, exceeding $12 billion dollars.

[4] Other generic drug companies have also sought to copy Lipitor® by filing ANDAs seeking FDA approval to sell generic atorvastatin tablets before the '995 patent expires. Pfizer has sued all of these companies in Delaware. (Mulveny Decl. ¶¶ 2-5, Exs. A-D.) One such case has gone to trial and is reported as *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495 (D. Del. 2005) (Mulveny Decl. ¶ 2, Ex. A).

21; OpenBr at 7-8.) In its ANDA, Apotex provided a "Paragraph IV" certification alleging that Apotex's proposed generic copy of Lipitor® would not infringe certain of Pfizer's patents and that these Pfizer patents are invalid. (D.I. 31 [Tao Decl.] ¶¶ 21-22, Ex. A, Original Notice Letter; D.I. 30 [Phillips Decl.] ¶ 20, Ex. S, RE667 Notice Letter; OpenBr at 7-8.)

Apotex's submission of its ANDA for generic atorvastatin tablets under 21 U.S.C. § 355(j) infringed Pfizer's patents pursuant to 35 U.S.C. § 271(e)(2)(A).

B. Apotex's ANDA Notice Letters, which are a critical part of its ANDA and serve as the basis for Pfizer to bring this lawsuit, were sent to Pfizer's Delaware counsel in Wilmington, Delaware

As part of its ANDA, Apotex was required to notify Pfizer of the submission in what is called an "ANDA notice letter". 21 U.S.C. § 355(j)(2)(B). In its ANDA notice letter, Apotex stated as the basis for its Paragraph IV certification that its proposed generic atorvastatin product would not infringe Pfizer's patents and that Pfizer's patents are invalid. (D.I. 31 [Tao Decl.] ¶¶ 21-22, Ex. A, Original Notice Letter; D.I. 30 [Phillips Decl.] ¶ 20, Ex. S, RE667 Notice Letter.) Apotex voluntarily sent its ANDA notice letter, as required by § 355(j)(2)(B), to Pfizer's Delaware counsel, Robert G. McMorrow, Jr. (D.I. 31 [Tao Decl.] ¶¶ 21-22, Ex. A, Original Notice Letter; D.I. 30 [Phillips Decl.] ¶ 20, Ex. S, RE667 Notice Letter; OpenBr at 7-8.)[5] Pursuant to § 355(j)(5)(C), Apotex's ANDA notice letter also contained a purported offer of confidential access that is required if Apotex were to assert a declaratory judgment action against Pfizer. (D.I. 31 [Tao Decl.] Ex. A at 3.) The offer of confidential access was limited to attorneys from one outside law firm representing Pfizer. (*Id.*) Presumably, Apotex sent its ANDA notice

[5] Apotex's assertion that "nothing, repeat nothing, concerning that ANDA, or anything else giving rise to this action occurred anywhere near Delaware" is belied by the fact that Apotex sent its ANDA notice letter to Pfizer's Delaware counsel, Robert G. McMorrow. (*Compare* D.I. 30 [Phillips Decl.] ¶ 20, Ex. S and D.I. 31 [Tao Decl.] ¶ 22, Ex. A *with* OpenBr at 13.) Apotex does not contest intentionally sending its ANDA notice letters to Delaware, however, it now says it did so as a "courtesy" (OpenBr at 7-8.)

letter to Pfizer's Delaware counsel, Mr. McMorrow, in an effort to extend the offer of confidential access to Mr. McMorrow and thus satisfy § 355(j)(5)(C).

Upon receipt of Apotex's ANDA notice letter, Pfizer initiated this lawsuit against Apotex Inc. and its Delaware entity—Apotex Corp.—in the District of Delaware for infringement of the '995 patent.[6] In filing that suit, Pfizer designated two pending cases in Delaware against Teva Pharmaceuticals—also involving an ANDA for atorvastatin and the infringement of the '995 patent—as related cases. (*See* Mulveny Decl. at ¶¶ 3-4, Exs. B-C; Mulveny Decl. ¶ 6, Ex. E, Civil Cover Sheet.) Moreover, Pfizer brought suit in Delaware also because this Court had already decided a dispute over an ANDA filed by Ranbaxy Laboratories Ltd., *et al.* for generic atorvastatin which this Court found infringed the '995 patent (Ranbaxy's ANDA also infringed another Pfizer patent that Apotex is not challenging in its ANDA.) *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, C.A. No. 03-209 (JJF), 405 F. Supp. 2d 495 (D. Del. 2005) (Mulveny Decl. at ¶ 2, Ex. A.) Pfizer filed additional suits in the Delaware Court for infringement of the '995 patent based on ANDAs filed by Cobalt Pharmaceuticals, CA 07-790 (JJF), now resolved by settlement. (Mulveny Decl. at ¶ 5, Ex. D.) This case is therefore the fourth suit filed by Pfizer in Delaware on the '995 Lipitor® patent. Apotex's assertion that Pfizer decided to shop around and select Delaware (OpenBr at 2) is belied by Pfizer's prior litigations involving the '995 patent which have been pending continuously in the Delaware District Court over more than six years.

[6] Apotex Corp. is a Delaware corporation. (Mulveny Decl at ¶ 7 Ex. F), and Apotex's present contention that Apotex Corp. has nothing to do with the ANDA at issue in this case, (*see* OpenBr at 2), is belied by the fact that Apotex Corp. joined Apotex Inc. in filing a counterclaim for declaratory judgment against Pfizer in the Northern District of Illinois based on the same ANDA. (D.I. 30 [Phillips Decl.] ¶ 3, Ex. B.) Thus, Apotex's present contention that Apotex Corp. has no involvement in Apotex's ANDA for generic atorvastatin does not match the actions of its Delaware affiliate in Illinois. (*Id.)* Pfizer has not had discovery and thus is unable to confirm Apotex Corp.'s participation in this ANDA and its filing.

C. Apotex Inc.'s business is generic medicines and as part of this business it regularly sells these medicines in Delaware

Apotex Inc.'s business is generic medicines. (OpenBr at 6.) Apotex is a Canadian company that manufactures and sells generic drugs worldwide through its Apotex Group of companies. (OpenBr at 6-7; *see also* Mulveny Decl. at ¶ 8, Ex. G at 1.) Apotex Inc. proclaims itself to be "the largest Canadian-owned pharmaceutical company," and "has grown to employ over 6,800 people in research, development, manufacturing and distribution facilities world-wide." (Mulveny Decl. at ¶ 8, Ex. G at 1.) From its inception, Apotex Inc. was set up to manufacture generic drugs for export into the United States: "This site [Etobicoke Canada] established in 1993 to service the US market" (*Id.* at 2), and further, as set forth on the Apotex Corp. website, "Apotex Corp. is the US company that markets the product of Apotex Inc." (Mulveny Decl. at ¶ 9, Ex. H.) Apotex Inc. does not dispute these statements and it has repeatedly admitted that its generic medicines have been continuously and systematically sold in Delaware.[7] In addition, Apotex Corp. is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" pursuant to 24 Del. C. § 2540. (Mulveny Decl. at ¶ 15, Ex. N.) Very plainly, Apotex Corp. is acting as the representative and agent of Apotex Inc. to effect these sales in Delaware.

[7] (Mulveny Decl. at ¶ 10, Ex. I) (Apotex Inc. Answer to Sanofi-Aventis Complaint) at ¶3 (admitted that "Apotex Inc. manufactures numerous drugs that are sold and used in [Delaware]"); (Mulveny Decl. at ¶ 11, Ex. J) (Apotex Inc. Answer to Senju Complaint) at ¶8 (admitted that "Apotex Inc. manufactures numerous drug products for sale and use in the United States including [Delaware]"); (Mulveny Decl. at ¶ 12, Ex. K) (Apotex Inc. Answer to Allergan Complaint) at ¶4 (admitted that "Apotex, Inc. [*sic*] manufactures numerous generic drugs for sale and use throughout the United States, including [Delaware]"); (Mulveny Decl. at ¶ 13, Ex. L) (Apotex Inc. Answer to MedPointe 2007 Complaint) at ¶3 (admitted that "Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in [Delaware]"); (Mulveny Decl. at ¶ 14, Ex. M) (Apotex Inc. Answer to Medpointe 2006 Complaint) at ¶3 (admitted that "Apotex Inc. manufactures generic drug products that are approved by the [FDA] and that the approved drug products are sold in the United States.").

D. In carrying out its business of selling generic medicines in the United States, Apotex Inc. also conducts substantial business in Delaware by litigating patents to obtain FDA approval and it has frequently availed itself of Delaware Courts by filing counterclaims

A *generic* drug company's need to litigate patents covering FDA-approved branded drug products is the central feature of its business model. Following the rights, requirements, and procedures of the Hatch-Waxman Act, including all its enabling regulations, the *sine qua non* of companies like Apotex Inc. is the litigation of patents owned by branded drug companies. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002) (explaining Hatch-Waxman Act scheme); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1325-27 (Fed. Cir. 2001) (same).

Apotex Inc. admits that it has been a party to eleven other ANDA-related patent suits in Delaware. (OpenBr at 17-18.) Apotex Inc. further admits that it has consented to (or not opposed) jurisdiction in Delaware in nine of the past eleven cases where it has been a party. (OpenBr at 17-18.) In one, Apotex Inc. was a plaintiff in a declaratory judgment suit. (Mulveny Decl. ¶ 16, Ex. O.) In eight of the Delaware cases, Apotex Inc. answered the Complaint, raised Counterclaims, and never challenged personal jurisdiction. (Mulveny Decl. ¶¶ 10-14, 17-19, Exs. I-M, P-R.) Apotex thereby affirmatively sought relief in Delaware courts.[8] Moreover, in February of 2009, after filing its present motion contesting this Court's personal jurisdiction over it, Apotex Inc. nevertheless again consented to personal jurisdiction in this District. (Mulveny Decl. ¶ 17, Ex. P.) In addition, Apotex Inc. has recently, unequivocally admitted in another ANDA patent case that personal jurisdiction over it was proper in this District. (Mulveny Decl. ¶ 12, Ex. K at ¶ 8.) In the nine Delaware ANDA cases, Apotex Inc. engaged the services of various

[8] Under 8 Del. C. § 371, Apotex Inc. was required to qualify as a foreign corporation to do business in Delaware by making the required filings with the Secretary of State of Delaware, absent which the Secretary of State is deemed its agent. Under 8 Del. C. § 383, Apotex Inc. was required to comply with § 371 in order to file and maintain these counterclaims.

Delaware law firms to represent it and repeatedly entered this State to further its primary business activity before this Court. (Mulveny Decl. ¶¶ 10-14, 16-19, Exs. I-M, O-R.)

E. Apotex Inc. attempts to avoid jurisdiction in Delaware by designating its Chicago, Illinois litigation counsel to be its agent for service of process

By its own admission, Apotex Inc. is a Canadian corporation, with all of its facilities and offices located in Canada. (OpenBr at 6.) Apotex Inc. contends that it conducted all of the underlying activities leading up to its instant ANDA filing in Canada. (OpenBr at 12, D.I. 31 [Tao Decl.] ¶¶ 4-5, 17-18.) Further, Apotex Inc. contends that, if its ANDA is approved by the FDA, it will not be directly selling generic atorvastatin in the United States. (D.I. 29, at 11-12; D.I. 31 [Tao Decl.] ¶¶ 12-13.) In fact, Apotex Inc. alleges that everything supporting its ANDA occurred in Canada. (D.I. 29, at 11-12; D.I. 31 [Tao Decl.] ¶¶ 17-18.)

According to Apotex Inc., its only contacts with the United States in connection with its ANDA are: (1) designating an agent in Chicago, Illinois -- its litigation counsel; (2) submitting or causing the submission of the actual ANDA to the FDA's offices in Maryland; and (3) sending Apotex's ANDA notice letter to Pfizer (and its Delaware counsel).

F. Apotex has selectively designated its agent in Chicago, Illinois for this case

Apotex Inc. has not consistently designated its Chicago litigation counsel as the agent for service of process regarding each individual ANDA it has submitted to the FDA. Instead, Apotex Inc. designates different agents for reasons known only to itself and thus tries to steer the resultant litigation to specific District Courts, on a case-by-case basis. If sued in a different jurisdiction, as here, Apotex Inc. either accepts that Court or denies that the Court has personal jurisdiction and seeks to transfer. (*See* Apotex's Transfer Motion, D.I. 32.) In short, claiming to act only outside of the United States, Apotex Inc. seeks through the designation of different agents in different locations for different ANDAs to manipulate the United States Judicial

System to its own benefit, while denying the injured pioneer drug company the right to litigate where the injury occurred.

G. Pfizer filed an identical protective suit in the Northern District of Illinois and has moved to stay that suit pending resolution of Apotex's Motion to Dismiss

Because Apotex Inc. identified its litigation counsel in Chicago, Illinois as its only agent for service of process regarding the instant ANDA, Pfizer filed a protective suit in the Northern District of Illinois alleging the same cause of action as this fist-filed case. (D.I. 30 [Phillips Decl.] ¶ 2, Ex. A.) Pfizer never intended that both cases would proceed simultaneously, and so informed Apotex's counsel, before its original and the instant motion was filed. Pfizer filed its Illinois case because of Apotex Inc.'s well-known game of jurisdictional Whac-A-Mole that it plays with its ANDA submissions in the United States.

Because Pfizer believes that jurisdiction is proper in Delaware, Pfizer has filed a motion to stay the action in the Northern District of Illinois pending resolution of Apotex's Motion to Dismiss. This motion has been fully briefed and is now pending before the Illinois Court.

V. ARGUMENT

While the Supreme Court views the tortious act of filing an ANDA as "highly artificial", the ANDA filing is a "real act" with "actual" and "serious" consequences. *Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 833-34 (Fed. Cir. 1999). Apotex's ANDA filing, seeking approval to market Lipitor® before expiration of Pfizer's applicable patents, clearly gives Pfizer the right to bring a lawsuit in a Federal District Court for the tort of patent infringement. The question at hand, therefore, is ***where*** can Pfizer bring a lawsuit seeking redress for Apotex's tort?

The answer is Delaware.

This Court has jurisdiction over Apotex because Delaware's Long-Arm Statute, 10 Del. C. § 3104(c), permits it and the exercise of jurisdiction over Apotex meets all Constitutional requirements for Due Process.

A. Jurisdiction is proper when Delaware's Long-Arm Statute permits and the exercise of jurisdiction complies with Due Process of Law

In a patent dispute, Federal Circuit law controls the personal jurisdiction analysis. *Hildebrand v. Steck Mfg. Co.*, 279 F.3d 1351, 1354 (Fed. Cir. 2002) (citing *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1564-65 (Fed. Cir. 1994) (other citations omitted)). The Federal Circuit follows the two-part test established by the Supreme Court. *Hildebrand*, 279 F.3d at 1354. Under this test, personal jurisdiction over an out-of-state defendant involves two inquiries: (1) whether the forum's long-arm statute confers jurisdiction; and (2) whether the assertion of personal jurisdiction comports with Constitutional requirements for due process. *Id.* (citing *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). In determining the jurisdictional question, the Court must accept as true the allegations in the complaint. *W.L. Gore & Assocs., Inc. v. Label Techs., Inc.*, C.A. No. 08-111-GMS, 2009 WL 1372106, at *2 (D. Del. May 15, 2009) (citing *Altech Indus., Inc. v. Al Tech Specialty Steel Corp.*, 542 F. Supp. 53, 55 (D. Del. 1982)). The plaintiff bears the burden of alleging facts sufficient to make a prima facie showing of personal jurisdiction over the defendant. *W.L. Gore*, 2009 WL 1372106, at *2. To meet this burden, the plaintiff must adduce facts which establish with reasonable particularity that jurisdiction over the defendant exists. *Id*.

1. The Delaware Long-Arm Statute grants this Court jurisdiction over Apotex Inc.

The Delaware long-arm statute has been construed to provide jurisdiction to the maximum extent possible in order to provide residents a means to redress against those not subject to personal service within the State. *Boone v. Oy Partek Ab*, 724 A.2d 1150, 1156-57

(Del. Super. 1997), *aff'd*, 707 A.2d 765 (Del. 1998). The Delaware Supreme Court has construed the long-arm statute broadly to confer jurisdiction to the maximum extent possible under the Due Process Clause. *Hercules Inc. v. Leu Trust & Banking (Bahamas) Ltd.*, 611 A.2d 476, 480 (Del. 1992). However, "the Delaware Supreme Court has not collapsed the analysis under the Delaware long-arm statute into the constitutional due process analysis." *ICT Pharms., Inc. v. Boehringer Ingelheim Pharms., Inc.*, 147 F. Supp. 2d 268, 271 n.4 (D. Del. 2001).

The Delaware statute, 10 Del. C. § 3104(c), provides:

> (c) As to a cause of action brought by any person arising from any of the acts enumerated in this section, *a court may exercise personal jurisdiction over any nonresident*, or a personal representative, *who in person or through an agent*:
> (1) *Transacts any business or performs any character of work or service in the State*;
> (2) Contracts to supply services or things in this State;
> (3) *Causes tortious injury in the State by an act* or omission *in this State*;
> (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any persistent course of conduct in the State or *derives substantial revenue from services, or things used or consumed in the State*….

10 Del. C. § 3104(c) (emphasis added). The Delaware Courts have also held that the statute is to be construed liberally, thus favoring the exercise of jurisdiction. *Waters v. Deutz Corp.*, 460 A.2d 1332, 1335 (Del. Super. 1983); *Mobil Oil Corp. v. Advanced Envt'l Recycling Techs., Inc.*, 833 F. Supp. 437, 443-4 (D. Del. 1993). Federal Courts in this District, moreover, have given an expansive interpretation to the long arm statute, ruling that § 3104(c) must be construed as conferring jurisdiction to the maximum perimeters of the Due Process Clause. *Transportes Aereos de Angola v. Ronair, Inc.*, 544 F. Supp. 858, 864 (D. Del. 1982).

Delaware's Long-Arm Statute is a "single act" statute, meaning that jurisdiction can be imposed on a non-resident defendant who engages in a single transaction in the forum state. *Id.*

at 864. Here, Apotex has committed acts directly related to this lawsuit in Delaware which therefore confer jurisdiction over it in Delaware under the "specific jurisdiction" theory.

(a) There is specific jurisdiction in Delaware due to Apotex Inc.'s direct contacts with the State that are the basis for this lawsuit.

When a non-resident defendant's contacts with the forum state are related to or give rise to the cause of action, a court may exercise what is called "specific jurisdiction". The court can assert specific jurisdiction over a nonresident defendant that has "'*purposefully directed' his activities at residents of the forum* and the litigation results from alleged injuries that 'arise out of or relate to' those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472-3 (1985) (emphasis added, citations omitted). Unlike the standard for claims of general jurisdiction, due process does not require a plaintiff asserting specific jurisdiction to show that a defendant's contacts with the forum state are "continuous and systematic." Indeed, the Federal Circuit has acknowledged that specific jurisdiction may be based on a defendant's "isolated and sporadic" activity within the forum state. *See Silent Drive, Inc. v. Strong Indus., Inc.*, 326 F.3d 1194, 1200 (Fed. Cir. 2003) (citing *Burger King*, 471 U.S. at 472-73).

Delaware State Courts have interpreted section 3104(c)(1) to be a specific jurisdiction provision of the Delaware long-arm statute. *Outokumpu Eng'g Enters., Inc. v. Kvaerner EnviroPower, Inc.*, 685 A.2d 724, 729 (Del. Super. 1996). Specific jurisdiction requires that there be a "nexus" between the plaintiff's cause of action and the conduct of the defendant that is used as a basis for jurisdiction. *See Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414, 414 n.8 (1984); *Boone v. Oy Partek Ab*, 724 A.2d 1150, 1155 (Del. Super. 1997). Accordingly, to show specific jurisdiction over Apotex, Pfizer need only show that Apotex specifically directed its activity at a Delaware resident and that this claim arises out of that

activity. As shown below, this Court has specific jurisdiction over Apotex for at least two reasons.

(1) Apotex Inc. voluntarily sent its required ANDA Notice Letters to Pfizer's Delaware Counsel that served as the basis for Pfizer bringing this lawsuit

First, by knowingly and voluntarily sending its ANDA notice letters to Pfizer's Delaware counsel, Robert G. McMorrow, Jr., Apotex Inc. has conducted a necessary part of its business of seeking FDA approval for generic atorvastatin in the State of Delaware.[9] 21 U.S.C. § 355(j)(2)(B)(i) ("An applicant ... shall include in the application a statement that the *applicant will give notice as required* by this subparagraph.") (emphasis added); (D.I. 31 [Tao Decl.] ¶¶ 21-22, Ex. A; D.I. 30 [Phillips Decl.] ¶ 20, Ex. S.) This act, an integral part of Apotex Inc.'s infringement, is directly connected to the dispute at hand because the ANDA notice letter provides Pfizer the grounds to bring suit against Apotex Inc. and Apotex Corp.

The notice letter also contained an offer of confidential information to Pfizer's outside counsel. (D.I. 31 [Tao Decl.] ¶¶ 21-22, Ex. A at 3; D.I. 30 [Phillips Decl.] ¶ 20, Ex. S at 3.) The offer, if in proper form, is intended to enable Apotex to maintain a counterclaim against Pfizer. *See* 21 U.S.C. § 355(j)(2)(C)(i). Thus, Apotex Inc. directly contacted Pfizer's Delaware counsel with an offer of confidential access as part of its overall effort to obtain FDA approval to sell generic atorvastatin. Accordingly, the notice letter and the offer of access provide a basis for this Court's jurisdiction over Apotex Inc. pursuant to 10 Del. C. § 3104(c)(1) as they were sent as part of Apotex's overall business of obtaining FDA approval to sell generic atorvastatin.[10]

[9] That Apotex Inc. now asserts that it sent its ANDA notice letters to Pfizer's Delaware counsel as a "courtesy" is immaterial to the analysis. There is no "courtesy copy" exception to the contacts creating specific jurisdiction.

[10] In support of its Motion to Dismiss, Apotex Inc. does not deny sending its ANDA notice letters (and offers of confidential access) to Pfizer's Delaware counsel. Instead, it argues that the letters *per se* are not torts. Apotex Inc. is confusing the issue. Pfizer contends that the letters were sent to Delaware as a required part of Apotex Inc.'s overall ANDA and its business of obtaining FDA approval to sell generic atorvastatin. Thus, the letters create specific

(2) Apotex has caused a tort in Delaware by injuring Pfizer with its ANDA submission

Second, Apotex Inc.'s filing of its ANDA is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This act of infringement is a tort. *Zeneca*, 173 F.3d at 832. And this tort occurred in Delaware. *See Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1468 (D. Del. 1991) ("The situs of the injury of patent infringement ... is the place of the patent holder's residence."); *Acrison, Inc. v. Control & Metering Ltd.*, 730 F. Supp. 1445, 1448 (N.D. Ill. 1990) ("Damage to intellectual property rights (infringement of a patent, trademark or copyright) by definition takes place where the *owner* suffers the damage.") (emphasis in original); *and see Honeywell, Inc. v. Metz Apparatewerke*, 509 F.2d 1137, 1142 (N.D. Ill. 1975) ("[I]t is now well settled that the term 'tortious act' inevitably includes the concept of injury, and ... the situs of the tort is the place where the injury occurs). Thus, because Pfizer is a Delaware corporation, Apotex's ANDA submission caused tortious injury in Delaware and confers jurisdiction over Apotex pursuant to 10 Del. C. § 3104(c)(3).

While the Federal Circuit in *Beverly Hills Fan* disagreed with the theory that the situs of injury from patent infringement is where the patentee resides and found jurisdiction where the infringing sale occurred, *see Beverly Hills Fan*, 21 F.3d at 1570-71, the Federal Circuit's decision in *Beverly Hills Fan* is limited to "traditional" patent infringement under 35 U.S.C. § 271(a) and should not be extended to the "highly artificial" infringement created by § 271(e)(2) that is the subject of this case. *Beverly Hills Fan*, 21 F.3d at 1571 (holding "*in a case such as this*, the situs of the injury is the location . . . of the infringing sales in Virginia.") (emphasis added). Here, there has been no actual infringing sale by Apotex in the United States (because Apotex lacks the required FDA approval), only the "highly artificial" patent infringement under

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jurisdiction over Apotex Inc. under § 3104(c)(1) (a court may exercise personal jurisdiction over any nonresident who "transacts any business or performs any character of work or service in the State").

§ 271(e)(2) due to Apotex's ANDA filing has occurred. Thus, the holding of *Beverly Hills Fan* is not dispositive of the jurisdictional analysis in this case. Further, the Federal Circuit's ruling in *Beverly Hills Fan*, which suggests the ANDA infringement would occur at the FDA's offices in Maryland, is in tension with the Federal Circuit's decision in *Zeneca* that the ANDA submission does not create personal jurisdiction to bring suit under § 271(e)(2) in the district where the FDA's offices are located. *Zeneca*, 173 F.3d at 831.[11] In fact, the Federal Circuit's *Zeneca* decision recognizes that "traditional infringing activity no longer counts as infringing" under the ANDA statute. *Zeneca*, 173 F.3d at 833. Therefore, such "traditional infringing activity"—such as the location of the manufacture, development, or sale of infringing products—cannot have any bearing on the jurisdictional analysis for ANDA cases.[12]

In the absence of any controlling Federal Circuit precedent (and in view of the conflicting precedent in *Zeneca* and *Beverly Hills Fan*), this Court's ruling in *Applied Biosystems* remains controlling. Accordingly, the patent infringement created by Apotex's ANDA submission caused tortious injury in Delaware because that is where Pfizer—the patentee and NDA holder—resides.

(b) There is general jurisdiction in Delaware over Apotex

Even when the cause of action does not arise out of or relate to the foreign corporation's activities in the forum State, Due Process is not offended by a State's subjecting the corporation to its *in personam* jurisdiction when there are sufficient contacts between the State and the foreign corporation. *Perkins v. Benguet Consol. Min. Co.*, 342 U.S. 437 (1952); *see Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 779-780 (1984). General jurisdiction refers to the

[11] Apotex subtly suggests that jurisdiction would be proper in Maryland because that is where Apotex filed its ANDA (OpenBr at 12.) This is directly contrary to the Federal Circuit's ruling in *Zeneca*.

[12] Apotex's argument that it has not sold any generic atorvastatin in Delaware is specious. The FDA has not granted Apotex permission to sell generic atorvastatin anywhere in the United States, so it is understandable that no products have yet been sold in Delaware. This argument is also disingenuous as it assumes that ANDA infringement is the same as any other patent infringement. As Apotex explains in its opening brief, ANDA infringement is "highly artificial" as no actual infringement has actually occurred. (OpenBr at 5-6.) Therefore, the fact that Apotex has not sold any infringing products in Delaware is a red herring.

authority of a court to hear any cause of action involving a defendant, even when the cause of action has no relation to the defendant's contacts with the forum state. The defendant must have "continuous and systematic" contacts with the forum state in order for a court to assert general jurisdiction. *Helicopteros*, 466 U.S. at 414-16; *see also Deprenyl Animal Health, Inc. v. University of Toronto Innovations Found.*, 297 F.3d 1343, 1350 (Fed. Cir. 2002) ("Where a defendant's contacts are continuous and systematic, due process permits the exercise of general jurisdiction."). Apotex Inc.'s continuous and systemic contacts with Delaware arise from its generic medicine business in two ways: (1) from Apotex Inc.'s substantial ANDA litigation in Delaware that is necessary to obtain FDA approval to market its generic medicines; and (2) from actual sales of Apotex Inc.'s generic medicines in Delaware.

(1) Apotex transacts business in Delaware through its history of ANDA litigation in this Court

(*i*) ANDA litigation is Apotex's regular business activity

Apotex Inc. is one of the largest suppliers of generic drugs in the United States. Unlike other businesses where litigation is an occasional, unintended, and undesirable consequence of business activities, patent litigation is a regular and intended component of the ordinary business activities of companies seeking to sell their generic drug products in the United States. This business activity is an outgrowth of the legislative scheme, the "Hatch-Waxman Act," [13] that regulates competitive activity between research-based pharmaceutical companies like Pfizer and generic drug companies like Apotex Inc.

The legislation contemplates that a research-based pharmaceutical company will conduct research and development to discover a new pharmaceutical product, seek to patent it, proceed to

[13] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified at* 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

conduct lengthy and expensive human clinical trials to establish the safety and efficacy of the drug, and file a New Drug Application ("NDA") with the FDA. If approved, the innovator company will be given permission to market the new drug in the United States.

The Federal Circuit has described the Hatch-Waxman Act and the ANDA litigation procedure in *Andrx Pharms.*, 276 F.3d at 1370-71, and *Mylan*, 268 F.3d at 1325-27. As explained there, under the statute, a generic drug manufacturer is permitted to seek FDA approval to market a generic copy of an innovator's FDA-approved new drug without submitting results of its own long and expensive clinical testing of the innovator's product. The generic drug company must simply show that its proposed generic copy is bioequivalent, which generally means that the copy contains the same active substance, it will be given to patients in the same dosage form, and it will provide the same levels of active ingredient in the blood as the approved product. The generic manufacturer is allowed under statutory "safe-harbor" provisions to use the innovator's patented product in testing to generate data for FDA-submission. 35 U.S.C. § 271(e)(1).

The generic drug maker may file an ANDA containing bioequivalence data to seek FDA permission to market the generic copy upon expiration of the innovator's patent. 21 U.S.C. § 355(j)(2)(A). A generic drug manufacturer may also seek FDA approval to market a generic copy of an approved, patented drug prior to expiration of all patents covering the drug. *Id.* If the generic drug manufacturer seeks permission to market the generic copy before patent expiration, it may do so by certifying to the FDA that it will not infringe any valid and enforceable claim of the innovator's patent (a so-called "Paragraph IV" certification) and thereafter notifying the patent owner as required by the enabling regulations. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If, after receiving the Paragraph IV certification notice, the patent owner files suit for infringement

within 45 days, the statute imposes an automatic 30-month stay of FDA approval of the ANDA to allow the court to resolve the patent issues. 21 U.S.C. § 355(j)(5)(B)(iii).

Lucrative rewards await generic drug companies making Paragraph IV certifications, and the companies have strong financial incentives to submit ANDAs having them. The reason is straightforward. Under the statute, the first generic drug manufacturer to file an ANDA having a Paragraph IV challenge is awarded 180 days of generic marketing exclusivity if the challenge is successful and the generic product is launched prior to the expiration of the patent. 21 U.S.C. § 355(j)(5)(B)(iv).

The practice that has grown up under this legislative scheme is one where the patent on virtually every important new pharmaceutical product is challenged by one or more generic drug companies racing to file ANDAs having Paragraph IV certifications and actively litigating the patent validity, enforceability, and infringement issues in federal district court. Thus, whereas innovators like Pfizer gain access to new products through business activities conducted in the laboratory related to product development, generic drug makers like Apotex Inc. gain access to new products through business activities regularly, systematically, and foreseeably conducted in Federal Courts.

The Federal District Court in Delaware is no stranger to this type of litigation. And it is no stranger to litigation involving Apotex Inc., including numerous claims asserted by Apotex Inc. in counterclaims. Indeed, this Court has become a favored forum for this kind of litigation for plaintiffs and defendants alike. The preference arises from the historical reputation of judges in this District for excellence and sophistication in patent matters and this District's practice of bringing these matters to trial before expiration of the 30-month stay of FDA approval. Not surprisingly, therefore, many generic drug companies that could challenge personal jurisdiction

in this District choose instead to purposefully avail themselves of the benefits of litigating ANDA cases in Delaware by voluntarily appearing here and even filing counterclaims here.

Apotex Inc. has engaged in this activity in this District. Apotex Inc. has thus engaged in a regular component of their generic drug business—ANDA litigation—here in Delaware, and should, therefore, be found to be generally present in this district.

(*ii*) Apotex is conducting its ANDA litigation business in Delaware

Apotex Inc.'s actual litigation decisions, public statements, and activities in Delaware Courts—all advancing its business interests by engaging in ANDA litigation—amply illustrate the point. The filing of ANDAs seeking approval to market patented drugs before the applicable patents expire, with Paragraph IV certifications challenging the patents and the resultant federal court litigation are a key part of Apotex Inc.'s regular business activities.

As Apotex Inc.'s Chairman and Chief Executive Officer, Dr. Bernard Sherman, testified during a hearing before a committee of the United States House of Representatives:

> At Apotex, we believe generic companies should endeavor to bring generics to market at the earliest possible time, and that the legislative and regulatory framework should facilitate, not obstruct, early generic entry. Our record in advocating for such a public policy framework, from our support for a district court trigger for exclusivity rather than an appellate trigger, our pursuit of declaratory judgment actions, our efforts in the courts to vacate anti-competitive settlements, our pursuit of infringement verdicts even where there is no guaranteed benefit to us, and our opposition to patent settlements, is unique and unmatched among generic manufacturers.
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>
> Year after year, Apotex has tirelessly litigated to bring products to market... .

(Mulveny Decl. ¶ 20, Ex. S, Protecting Consumer Access to Generic Drugs Act of 2007: Hearings on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the House Comm. on Energy and Commerce, 110th Cong. (May 2, 2007) (statement of Barry Sherman, Chief Executive Officer of Apotex Inc.), *reprinted in* 2007 WL 1290291, at *1-2, 5.) As a 2002 published article observed:

> In a single word: litigation. Apotex is famous for suing anybody who tries to stop it selling [sic] a generic version of a bestselling drug. No matter that the inventors' patents may have years to run; Mr. Sherman is a master at picking holes in such claims, and then pursuing his interests in court. His company is embroiled in almost 100 lawsuits and spends more than $10m a year in legal fees.

(Mulveny Decl. ¶ 21, Ex. T, *Generic Gadfly: Barry Sherman and His Generic-Drug Company, Apotex, Have Put Big Pharma in a Tizzy*, 363 ECONOMIST at 65 (Apr. 13, 2002).)

In just the past six years, Apotex Inc. has been a party to over 60 patent suits in the United States. (Mulveny Decl. ¶ 22, Ex. U.) Apotex Inc. admits that it has been a named defendant in at least eleven ANDA cases in Delaware. (OpenBr at 17.) In nine of these cases, Apotex Inc. either did not contest or otherwise consented to jurisdiction in Delaware. (OpenBr at 18.) Notably, Apotex Inc. was the plaintiff in a declaratory judgment suit against Pfizer in this Court. (Mulveny Decl. ¶ 16, Ex. O.) As a result, Apotex Inc. obtained a covenant not to sue and began selling a generic version of the pharmaceutical product at issue in that case, quinapril. (*Id.*; Mulveny Decl. ¶ 23, Ex. V, Fed. Cir. decision noting covenant not to sue; Mulveny Decl. ¶ 8, Ex. G at 23)

In eight of the Delaware cases, Apotex Inc. answered the Complaints, raised Counterclaims, and never challenged personal jurisdiction. (Mulveny Decl. ¶¶ 10-14, 17-19, Exs. I-M, P-R.) In February of this year, while simultaneously contesting this Court's jurisdiction over it in *this* case, Apotex Inc. again consented to personal jurisdiction in Delaware. (Mulveny Decl. ¶ 17, Ex. P.)

Quite significantly, less than a year ago, Apotex Inc. unequivocally admitted the propriety of personal jurisdiction over it in Delaware in an ANDA case indistinguishable from this one:

> 8. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants.

ANSWER: Admitted that the Court has personal jurisdiction over Apotex Inc. and Apotex Corp.; otherwise denied.

(Mulveny Decl. ¶ 12, Ex. K, at 3, ¶ 8.)

In those nine Delaware ANDA cases, Apotex Inc. engaged the services of Delaware law firms to represent it and presumably paid the law firms substantial sums. (Mulveny Decl. ¶¶ 10-14, 16-19, Exs. I-M, O-R.) While arguably an infrequent and isolated consent to suit may be explainable, Apotex has gone far beyond this point and has systematically and regularly resorted to Delaware Courts as an integral part of its generic drug business.

Very plainly, Apotex Inc.'s attempts to pick and choose its jurisdictions on a case-by-case basis at some time reach a point, as here, having elected to litigate in Delaware on such a frequent basis, that its self-serving efforts to avoid Delaware in *this* case should be rejected.[14]

Because Apotex Inc. actively conducts its ANDA litigation business in Delaware, and avails itself of the resources of the Delaware Courts and the Delaware legal community to advance its business purposes, it is amenable to service of process under the Delaware long-arm statute. *See, e.g.*, *Colonial Mortgage Serv. Co. v. Aerenson*, 603 F. Supp. 323, 327 (D. Del. 1985) (general jurisdiction held to exist where, inter alia, the defendant had "repeatedly invoked the benefits of the Delaware state courts to protect its interests" by filing suit in Delaware). In addition, because Apotex Inc. has demonstrated through its voluntary presence in the Federal District Court in Delaware that it could reasonably expect to be haled into court here and can, without undue burden, appear here, defend itself, and assert claims and counterclaims, the exercise of personal jurisdiction over Apotex Inc. comports with due process.

This case involves a Delaware plaintiff—Pfizer—and "Delaware has a strong preference in favor of affording its citizens, such as a Delaware resident in this case, a judicial forum and

[14] The only apparent distinction between the Delaware cases in which Apotex Inc. did not challenge jurisdiction and this case where it has challenged jurisdiction is the identity of the judges to whom the cases were assigned.

respecting their choice of forum." *Wright v. American Home Prods. Corp.*, 768 A.2d 518, 539 (Del. Super. 2000); *cf. Merck & Co. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 375 (D. Del. 2002) (stating that the case did not involve Delaware plaintiffs as a factor in concluding that Delaware has no interest in adjudicating the case).

(2) Apotex continuously and systematically sells its generic medicines in Delaware

According to their website, Apotex Inc. makes private label ranitidine (Zantac®) and omeprazole (Prilosec®) for sale in the United States. (Mulveny Decl. ¶ 8, Ex. G.) Apotex Inc. also sells some notable generic products in the United States: amlodipine besylate (Norvasc®), gabapentin (Neurontin®), Paroxetine (Paxil®), Carvedilol (Coreg®) pravastatin sodium (Pravachol®), quinapril (Accupril®), and sertraline (Zoloft®). (*Id.*) These are being offered for sale in Delaware. (Mulveny Decl. ¶ 24, Ex. W.) That Apotex Inc. may send these products into Delaware via its U.S. corporations does not mitigate the fact that a significant amount of Apotex Inc.'s products is being sold in Delaware stores to Delaware citizens. And Apotex Inc. has not argued that it does not intend for its products to be sold in Delaware. It sells its products throughout the United States and makes no effort to exclude Delaware from its national sales. Apotex Inc.'s products therefore are also necessarily being prescribed by Delaware doctors, used in Delaware hospitals and other facilities, are often substituted for brand products, and are taken by Delaware residents. According to data compiled from IMS, Apotex Inc. sold over 132,000 prescriptions totaling over $2.8 million in 2008 alone in Delaware. (*See* Mulveny Decl. ¶ 25, Ex. W.)

The Federal Circuit recognizes that sales and distribution of products in the forum state support general jurisdiction. *See LSI Industries, Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369,

1375 (Fed. Cir. 2000).[15] That defendant employed "multiple distributors in Ohio and nets several millions of dollars per year from sales in Ohio" (*Id.* at 1370), which the Federal Circuit held constituted "maintain[ing] 'continuous and systematic' contacts" with Ohio. *Id.* at 1375.

Whether the amount of income derived from the forum state is a small portion of the defendant's total income "is not decisive." *Hill v. Equitable Trust Co.*, 562 F. Supp. 1324, 1331 (D. Del. 1983). "Generally speaking, the appropriate inquiry under Section 3104(c)(4) is whether [the defendant], in absolute dollar amounts, 'derives substantial revenue' from Delaware." *Id.* (citations omitted). Moreover, even if the "revenue derived from Delaware is insubstantial, Section 3104(c)(4) provides for jurisdiction if the defendant's conduct is persistent or regular in Delaware, irrespective of the substantiality of the revenue derived from the State." *Id.* Accordingly, the *Hill* court found personal jurisdiction existed even though the defendant's income from transactions in Delaware amounted to only about $50,000. *Id.* Likewise, a recent ANDA case found general jurisdiction existed where the defendant's sales in the forum state over four years totaled approximately $6 million. *See Eli Lilly & Co. v. Mayne Pharma (USA) Inc.*, 504 F. Supp. 2d 387, 390-91 (S.D. Ind. 2007).

As the court recognized in *Eli Lilly*, "'[i]t is the overall nature of the activity, rather than its quantitative character', that must be analyzed to determine whether the court has personal jurisdiction." *Id.* at 395 (quotation omitted). Here, Apotex Inc. has actively directed its continuous and systematic business activities of litigating ANDAs and selling its products to Delaware.[16]

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[15] Apotex misses the point when it argues that the sales of its drugs in Delaware can only be considered under a "stream of commerce" theory that requires a showing of specific jurisdiction. (OpenBr at 19.) This is not so. As the Federal Circuit found in *LSI Industries*, the sale of millions of dollars of products in the forum state is sufficient to generate the "continuous and systematic" contacts giving rise to *general* jurisdiction. *LSI Industries*, 232 F.3d at 1375.

[16] Pfizer has not had the opportunity to discover the full details of Apotex's distribution network and the exact amount of Apotex's sales in Delaware. However, on information and belief, Pfizer contends that Apotex derives a

Equally important, presumably Apotex Inc. intends, if its ANDA is approved, to also sell its atorvastatin generic product in Delaware.

2. Exerting jurisdiction over Apotex complies with Due Process of Law

For the due process inquiry, the Federal Circuit applies the "minimum contacts" standard developed by the Supreme Court in *International Shoe*. *Hildebrand*, 279 F.3d at 1355. Under the *International Shoe* standard, due process requires that, in order to subject a defendant who is "not present within the territory of the forum" to personal jurisdiction, the court must first make sure that the party "ha[s] certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *See Int'l Shoe Co. v. Washington*, 326 U.S. at 316 (citations omitted).

To find that a defendant has sufficient "minimum contacts" with the forum state, the Supreme Court requires that a plaintiff must demonstrate either (a) specific or (b) general personal jurisdiction. *Helicopteros*, 466 U.S. at 414. As discussed above, Pfizer has established that this Court has both specific and general jurisdiction with respect to the Delaware Long-Arm statute. Thus, the constitutional test is also satisfied. *See Colonial Mortgage*, 603 F. Supp. at 327 ("The constitutional test for personal jurisdiction is similar in this instance to that applied under the statutory framework previously discussed").[17]

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substantial amount of income from the sales of its products in Delaware. And if Apotex's websites are to be believed, it uses Apotex Corp. to sell its products in the United States and in Delaware. As discussed in section V.B., *infra*, Pfizer reserves the right to obtain jurisdictional discovery if this Court believes it would be necessary to resolve Apotex's Motion to Dismiss.

[17] With respect to the three-prong specific jurisdiction Constitutional test set forth by the Federal Circuit, Pfizer has already established that: (1) Apotex Inc. purposefully directed its activities at residents of Delaware; and (2) this lawsuit arises out of or relates to Apotex Inc.'s activities. *3D Sys. Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1378 (Fed. Cir. 1998) (citations omitted). The third prong—that the assertion of personal jurisdiction is unreasonable and unfair—is Apotex Inc.'s burden to establish. *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1363 (Fed. Cir. 2001). To defeat jurisdiction, Apotex Inc. must make a compelling case that other considerations render the exercise of jurisdiction constitutionally unreasonable. *Id.*

The Court's exertion of personal jurisdiction over Apotex Inc. would not offend traditional notions of justice and fair play. In fact, to decline jurisdiction would legitimize Apotex Inc.'s strategy of hiding behind the Canadian border to not only cause harm to Delaware residents, but also to conduct its substantial business in Delaware while denying Delaware residents from seeking redress for Apotex Inc.'s harms in Delaware. The balance of fairness and justice clearly tip in Pfizer's favor.

Additionally, Apotex Inc. admits that it has consented to jurisdiction in Delaware in at least nine other cases. Apotex Inc. has even come to Delaware to sue Pfizer in the past. And it has frequently asserted counterclaims. Given its willingness to litigate in Delaware in the past, Apotex Inc. cannot now claim surprise at being sued by Pfizer in Delaware in this case.

In its Motion to Dismiss, Apotex Inc. complains that the exercise of jurisdiction in this case would "violate the most basic tenets of due process, thus requiring dismissal as a matter of law" because nothing about this action arose or occurred in Delaware and Apotex has no contact in Delaware. (OpenBr at 21.) Apotex goes so far as to insist that "nothing, repeat nothing" concerning its ANDA occurred "anywhere near Delaware." (OpenBr at 13.) Apotex's alleged total absence from Delaware is belied the following:

(1) Apotex sent its ANDA notice letters and offers for confidential access to Pfizer's Delaware counsel. The ANDA notice letters and offers for access are essential parts of its ANDA and they provided Pfizer the requisite notice to bring this suit.

(2) Apotex's ANDA submission is a tort committed in Delaware as that is where Pfizer resides. The tort of patent infringement is the very basis for this lawsuit.

(3) Apotex has continuous and systemic contacts with Delaware arising from its business of litigating patents here and in selling generic medicines here.

(4) Apotex has consented to litigating in Delaware on several times in the recent past. It is no stranger to this Court.

Apotex's substantial connections to Delaware, both in connection with its ANDA submission and those built up through its generic medicine business, confirm that the exercise of personal jurisdiction over Apotex does not offend Due Process under the Constitution.

Finally, despite having multiple opportunities to do so in the myriad of papers filed in this Court and in the Illinois Action, Apotex Inc. has not identified a single reason why it would be inconvenienced by litigating this case in Delaware. For all of its bluster about Illinois being the more appropriate forum and despite its unexplained—and not credible—contention that it designated Illinois counsel "[t]o preserve the resources of the parties and the courts" (OpenBr at 1), Apotex has not identified a single document, witness, or event located in Illinois related to this case. By contrast, Pfizer has brought all prior Lipitor® ANDA litigations in this Court. In contesting this Court's jurisdiction, Apotex has the burden to show that the exercise of jurisdiction would not be reasonable or fair. It has failed to meet this burden.

B. Pfizer is entitled to jurisdictional discovery to support its opposition of Apotex's Motion to Dismiss

Courts have recognized that facts which would establish personal jurisdiction over the defendant are often in the exclusive control of the defendant. *Compagnie des Bauxites de Guinee v. L'Union Atlantique S.A.*, 723 F.2d 357, 362 (3d Cir. 1983). As such, a plaintiff may be unable, without some discovery, to properly respond to a motion to dismiss pursuant to Rule 12(b)(2), and a court will therefore allow some discovery. *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n.13 (1977) ("[W]here issues arise as to jurisdiction or venue, discovery is available to ascertain the facts bearing on such issues."); *see also Fraley v. Chesapeake & Ohio Ry. Co.*, 397 F.2d 1, 3 (3d Cir. 1968) (finding the district court's refusal to permit discovery in aid of personal jurisdiction improper). The Third Circuit, which is the controlling authority on this point, mandates that jurisdictional discovery should be allowed unless the plaintiff's claim is "clearly

frivolous" *Bauxites*, 723 F.2d at 362 (citing cases). As discussed above, Pfizer's claim that this Court has jurisdiction over Apotex Inc. is not clearly frivolous. Therefore, Pfizer is entitled to jurisdictional discovery.

In the event that the Court finds that Pfizer has not met its burden to establish personal jurisdiction over Apotex Inc. based on the limited information presently available, Pfizer respectfully requests that it be granted leave to pursue jurisdictional discovery of Apotex Inc. and be provided a reasonable opportunity to supplement its brief in opposition to Apotex's Motion to Dismiss. This request is particularly appropriate with respect to the degree of ownership, control, and the overlap between Apotex Inc. and Apotex Corp. These facts would be directly relevant to the agency and alter ego claims that Pfizer has alleged in its amended complaint.

> 30. On information and belief, Apotex U.S.A. is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Apotex Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.
>
> 31. On information and belief, Apotex U.S.A., as the authorized agent of Apotex Inc. and/or in its own capacity, participated in the preparation and filing with the FDA of the Apotex ANDA for approval to market generic atorvastatin calcium in the United States.
>
> 32. On information and belief, Apotex Inc. develops and manufactures generic drugs and, directly or indirectly through Apotex U.S.A., markets, distributes, and sells its generic drugs throughout the United States, including the State of Delaware.

(D.I. 25, ¶¶ 30-32.) If the Court finds that jurisdictional discovery is warranted, Pfizer will file a formal motion requesting said discovery.

VI. CONCLUSION

Accordingly, for all the above reasons, Apotex's Motion to Dismiss should be denied. If the Court finds that it does not have personal jurisdiction over Apotex Inc., in the interests of justice, Pfizer requests that Apotex's Motion to Dismiss be denied and, as Apotex itself has

alternatively requested, that this case be transferred to the Northern District of Illinois to be consolidated with the concurrent Illinois Action.[18]

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Dated: May 26, 2009

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[18] If no personal jurisdiction over Apotex Inc. is found, transfer of this case to Illinois would resolve the indispensible party issue raised by Apotex. Thus the interests of justice favor transfer over dismissal.

CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2009, a true copy of the foregoing ***Plaintiffs' Brief In Opposition To Defendants' Motion To Dismiss For Lack Of Personal Jurisdiction*** was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and the document is available for viewing and downloading from CM/ECF:

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I hereby certify that on May 26, 2009, I have sent by U.S. Mail the foregoing document to the following non-registered participant:

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